UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,441	09/28/2001	Christopher E. Szymczak	MCP-284	5360

27777 7590 05/05/2005

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,441	SZYMCZAK ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-2, 4-14 and 16-29* is/are pending in the application.

4a) Of the above claim(s) *6,18,27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7-14,16,17,19-26 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

I. The rejection of claims under 35 USC 112, first paragraph, is not maintained in light of the amendment.

II. The rejection of claims under 35 USC 112, second paragraph, is maintained for the reasons of record.

III. The rejection of claims under 35 USC 102(b) rejection as being anticipated by Stevens et al. (US 5679376 A) is not maintained in light of the amendment.

IV. The rejection of claims under 35 U.S.C. 102(b) as being anticipated by Luber et al. (US 6103260 A) is not maintained in light of the amendment.

V. The rejection of claims under 35 U.S.C. 103(a) as being unpatentable over Kitsusho Yakuhin Kogyo KK (JP 398241) in view of Tobyn et al. (International Journal of Pharmaceutics 169 (1998) 183-194) is maintained for the reasons of record.

VI. The rejection of claims 16 and 17 under 35 U.S.C. 103(a) as being unpatentable over Kitsusho Yakuhin Kogyo KK (JP 398241) in view of Tobyn et al. (International Journal of Pharmaceutics 169 (1998) 183-194) and Stevens et al. (US 5679376) is maintained for the reasons of record.

Status of Application

1. By Amendment filed February 07, 2005, claim 1 has been amended; claim 3 has been cancelled; and claim 29 has been newly added. Claims 1-2, 4-5, 7-14, 16-17, 19-26 and 29 are currently pending for prosecution on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites that the weight ratio of simethicone to adsorbent is "at least about 1:2.00". The scope of the instant claim 2 encompasses "1:1.95, 1:1.96, 1:9.7, 1:9.8, 1:9.9, 1:2.00, 1:2.01, 1:2.02, 1:2.02, 1:2.03, 1:2.04, 1:2.05...1:2.20, 1:2.21...". The scope of the claim 2, for example "1:1.95, 1:1.96, 1:9.7, 1:9.8, 1:9.9, 1:2.00, 1:2.01, 1:2.02, 1:2.03, 1:2.04, 1:2.05", is broader than the scope of the claim 1, "at least about 1:2.22", for example "1:2.20, 1:2.21, 1:2.22, 1:2.23, 1:2.24, 1:2:25, 1:2:26, 1:2.27, 1:2.28, 1:2.29, 1:2.30...". As discussed above, claim 2 fails to further limit the subject matter of the claim 1. This inconsistency leads to lack of clarity of the claims as a whole.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-2, 4-5, 7-14, 16-17 and 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitsusho Yakuhin Kogyo KK (JP 398241) in view of Tobyn et al. (International Journal of Pharmaceutics 169 (1998) 183-194), and further in view of Stevens (US 5679376).

The claims read on a composition comprising an admixture of simethicone, silicified microcrystalline cellulose, and magnesium aluminometasilicates. Further limitations include a) the specific weight ratio of simethicone to a combination of silicified microcrystalline cellulose and magnesium aluminometasilicates; b) the specific concentration of simethicone; c) the

specific dosage concentrations of silicified microcrystalline cellulose and magnesium aluminometasilicates; and d) a hardness value of a tablet.

Kitsusho Yakuhin Kogyo KK teaches a method for preparing simethicone tablets by mixing and granulating simethicone with magnesium aluminum metasilicate. In particular, the formulation disclosed by the above Japanese patent requires at most 25% simethicone and 75% or greater silicate, binder (i.e., starch and lactose) and dispersing agents (i.e., carboxymethylcellulose). Further, the reference teaches that when the amount of simethicone exceeds 25%, there is tendency that a portion of the simethicone can be carried away, therefore the tablet workability is not desirable.

Tobyn discloses the advantage of using silicified microcrystalline cellulose in improving tablet workability such as "powder flow", "tablet strength", "lubricant sensitivity" and "wet granulation" (page 184, column 2, lines 4-9; page 193, column 2, lines 43-48).

The teaching of Kitsusho Yakuhin Kogyo KK differs from the claimed invention in i) the incorporation of silicified microcrystalline cellulose in said composition; ii) ""at least 30 wt% simethicone" in said composition; iii) the specific amounts of silicified microcrystalline cellulose and magnesium aluminometasilicates in said composition; and iv) the specific harness value of the tablet. To incorporate such teaching into the teaching of Kitsusho Yakuhin Kogyo KK, would have been obvious in view of Tobyn who teaches the advantage of using silicified microcrystalline cellulose as a pharmaceutical excipients to improve powder flow characteristic, lubricant sensitivity, tablet strength and better bulk physical properties.

One having ordinary skill in the art would have been motivated, with a reasonable expectation of success, to incorporate silicified microcrystalline cellulose having good free-

flowing and disintegrating properties (which is relatively new pharmaceutical excipients in the art) such that the tablet workability would be significantly improved. Furthermore, one having ordinary skill in the art would have been motivated to increase the amount of simethicone above 25% in the solid final blend for tabletting by incorporating silicified microcrystalline cellulose in said composition.

Although the prior art references are silent about the specific dosage amounts of active ingredients and the hardness value of tablet, the optimization of amounts of kwon active and inactive ingredients in a composition or the determination of optimum hardness value of the tablet is well considered within the skill of the artisan, absent evidence to the contrary.

With respect to claims 16 and 17,

The modified teaching of Kitsusho Yakuhin Kogyo KK includes all that is recited in claims 16 and 17 except for the incorporation of active pharmaceutical ingredients such as famotidine. Stevens teaches or suggests the use of simethicone and other pharmaceutical excipients in preparing oral solid dosage form containing H2 blockers (e.g,, famotidine). One having ordinary skill in the art would have known that simethicone is routinely combined with H2 blockers such as famotidine in solid oral dosage formulation art, and would have been motivated to further modify the teaching of Kitsusho Yakuhin Kogyo KK such that the better solid oral dosage form containing famotidine would be formulated. One having ordinary skill in the art would have been motivated to do this so that the tablet workability would be significantly improved.

Allowable Subject Matter

4. The following is a statement of reasons for the indication of allowable subject matter: As discussed above, the prior art references in combination (Kitsusho, Tobyn and Stevens) makes obvious of the ratio of simethicone; adsorbent including magnesium aluminometasilicate and silicified microcrystalline cellulose at least about 1:2.22. However, the prior references in combination does not provide sufficient guidance for the skill artisan to arrive at the claimed composition with the specific ratio of about 1: about 0.5 to about 0.85: about 0.9 to about 1.30 wt/wt (simethicone: magneisum aluminometasilicate: silicified microcrystalline cellulose).

Response to Arguments

5. Applicant's arguments filed February 07, 2005 have been fully considered but they are not persuasive.

Applicant's argument in the response takes the position that the interpretation of the claimed weight ratio relied on by the Examiner is contrary to the ordinary and customary meaning of the term "ratio". Applicant alleges that under the ordinary and customary meaning objectively provided by the technical dictionaries, the interpretation of the claimed weight ratio in claim 2 of "at least about 1:22" is properly interpreted as "at least the quotient 1:2.22" which is equivalent to the quotient 1/2.22.

Applicant's argument is not found persuasive. Although it may be true that the term "ratio" can be interpreted as "the quotient of two mathematical expressions", Merriam-Webster dictionary also defines the term "ratio" as "the relationship in quantity, amount, or size between two or more things : **PROPORTION**". In other words, the claimed ratio of simethicone to

adsorbent can be interpreted as the proportion of simethicone in relationship to adsorbent. Under the definition of the term "ratio" as "proportion", the claimed weight ratio of "at least about 1:2.22" is properly interpreted as "greater than or equal to about 1 part of simethicone in relationship to greater than or equal to about 2.22 part of adsorbent". Since the interpretation of the instant weight ratio of simethicone to adsorbent in claim 2 includes "1:1.95, 1:1.96, 1:9.7, 1:9.8, 1:9.9, 1:2.00, 1:2.01, 1:2.02, 1:2.02, 1:2.03, 1:2.04, 1:2.05...1:2.20, 1:2.21...", the scope of the claim 2 is broader than the scope of the claim 1, "at least about 1:2.22", for example "1:2.20, 1:2.21, 1:2.22, 1:2.23, 1:2.24, 1:2:25, 1:2:26, 1:2.27, 1:2.28, 1:2.29, 1:2.30...". As discussed above, claim 2 fails to further limit the subject matter of the claim 1. This inconsistency leads to lack of clarity of the claims as a whole.

Applicant's argument in the response takes the position that Tobyn fails to point out where in Tobyn even one experiment using simethicone is disclosed. Applicant alleges that the Examiner fails to provide any facts in Tobyn to indicate that simethicone, a viscous oil-like substance, could be adsorbed onto silicified microcrystalline cellulose, much less any facts indicating that silicified microcrystalline cellulose would have the same improved properties when formulated with simethicone.

Applicant's argument is not found persuasive. There is no dispute between the Examiner and the Applicant that Tobyn does not mention about using simethicone with siMCC or MCC. Tobyn was introduced as a reference to demonstrate the routine knowledge in utilizing siMCC and MCC, more preferably siMCC, during direct compression tableting. One having ordinary skill in the art would have known as taught by Tobyn that siMCC provides far more advantage as

pharmaceutical excipients for direct compression tableting than MCC, and would have been motivated, with a reasonable expectation of success, to incorporate silicified microcrystalline cellulose having good-flowing and disintegrating properties (which is relatively new pharmaceutical excipients in the art) such that the tablet workability would be significantly improved. Furthermore, one having ordinary skill in the art would have been motivated to increase the amount of simethicone above 25% in the solid final blend for tabletting by incorporating silicified microcrystalline cellulose in said composition.

The utilization of microcrystalline or carboxymethylcellulose in combination of colloidal silicon dioxide as pharmaceutical excipients for direct compressing tableting is well recognized in the art (see Stevens, especially column 4, lines 14-22 and column 5, lines 41-43; Ruber, especially column 4, lines 20-22 and 27-30). Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

With respect to Applicant's argument about the ratio of simethicone to adsorbent in Stevens, the Examiner believes that this issue was discussed in the Office Action mailed May 30, 2003 (page 7, para. 4-5), so the response discussed in the Office Action applies here as well.

Conclusion

6. Claim 29 is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

VICKIE KIM
PRIMARY EXAMINER

Brian Kwon
Patent Examiner
AU 1614